

Exhibit 58

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE JOHNSON & JOHNSON
TALCUM POWDER PRODUCT
MARKETING, SALES
PRACTICES AND PRODUCTS
LIABILITY LITIGATION**

This Document Relates to All Cases

Civil Action No. 3:16-md-2738-MAS-RLS

MDL No. 2738

**SECOND SUPPLEMENTAL EXPERT REPORT OF
SONAL SINGH, MD, MPH**

Dated: May 28, 2024

DocuSigned by:
Sonal Singh
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Sonal Singh, MD, MPH

I have updated Section V.4 on the cohort studies (Pg 10 to11) and the Bradford Hill viewpoints of *strength of association, consistency, biological gradient, plausibility and coherence* (Page 19-22) of my supplemental expert report dated November 15 , 2023 after reviewing the updated analysis by O'Brien and co-authors on data from Sister's Cohort study and the accompanying editorial.^{1,2}

Earlier O'Brien et al reported a positive association in their pooled analysis of cohort studies, which included the Sister cohort, but acknowledged the potential for misclassification of exposure and recall bias which biased their results towards the null.^{3,4} Exposure was only assessed at baseline and not updated during follow up in any of the cohort studies including the Sister Study. In this 2024 study they collected additional data on detailed lifetime exposure including ever use, frequent use, long term use (≥ 20 years), use during each decade for genital talc in the detailed fourth follow-up questionnaire for the Sister Study cohort.¹ They addressed the potential for misclassification of exposure and missing data by conducting a quantitative bias analysis with multiple imputation using well established epidemiologic methods of multiple imputation that have been in existence for decades.⁵ The quantitative bias analysis was carried out under several scenarios including a) no correction; b) correction of contradictory data on exposure status between the first and follow up questionnaire; c) correction of contradictory data plus categorizing missing data as exposed; and d) contradictory data correction with multiple imputation with chained equation of missing data to impute the exposure status of participants. The fourth scenario represented the most reliable estimate absent recall bias. Now that detailed follow-up data on exposure were available, they were able to illustrate the potential impact of recall bias, if it existed, under different assumptions of genital talc exposure. Further correction of recall bias after the quantitative bias analysis (scenario d) was conducted by estimating recall bias adjusted HR_{rb} under a wide range of assumptions : 1) recoding a proportion (10 %-90%) of ovarian cancer cases who used talc to be non-users; 2) recoding a proportion (10 %-90%) of ovarian cancer cases classified as non-frequent and short-term users to be non-users; and 3) recoding a proportion (5% to 25%) on non-cases classified as non-talc users to be infrequent and short term users. The HRs for genital talc use and ovarian cancer were estimated in a multivariable Cox proportional hazard model adjusted for race/ethnicity, education, BMI, age at menarche, birth control use, parity, menopausal status, hormone therapy, smoking status, alcohol use, and geographic region.

The proportion of participants reporting ever use (35% vs 27%), frequent use (18 % vs 7%) and long-term use (13 % vs 6 %) of genital talc increased substantially compared to the prior Sister cohort. The study added follow-up time [mean of 13.2 years (SD 2.9) vs a median of 9.6 years (interquartile range 8.4 to 11.1 years)], an additional 72 ovarian cancer cases (n=292 cases vs n= 220 cases) among genital talc users compared to data from the Sister Study in the prior pooled analysis.

The adjusted HR for genital talc users and ovarian cancer was statistically significantly elevated (HR 1.82, 95% CI 1.36 to 2.43) in the quantitative bias analysis accounting for contradictory data correction and multiple imputation (scenario d-best estimate) as shown in **Table 3**. For that scenario, the dose-response analysis showed a consistent and statistically significant increased risk of ovarian cancer for both frequent genital talc users (HR 1.99, 95% CI 1.43 to 2.78) and long-term genital talc users (HR 2.2, 95% CI 1.52 to 3.19) compared to never users. Both sometime use of genital talc (HR 1.56, 95% CI 1.09 to 2.22) and use for one decade only (HR1.48, 95% CI 1.06 to 2.06) was also associated with a statistically significantly increased risk of ovarian cancer. The tests for trend were statistically significant for both frequency and long-term genital talc use ($P_{\text{trend}} < 0.001$).

The analysis with additional correction for recall bias even under highly conservative assumptions (25% of non-frequent, short term talc users with ovarian cancer misreport their status, and 10% of non-cases who report no use are short term and infrequent users) was only slightly attenuated but also remained statistically significantly for ever users of genital talc (HR_{rb} 1.4, 95% CI 1.04 to 1.89), frequent users (HR_{rb}

1.81, 95% CI 1.29 to 2.53) and long term users of genital talc (HR_{rb} 2.01, 95% CI 1.39 to 2.91). The tests for trend were statistically significant for both frequent and long-term use, ($P_{trend}=0.001$). Both sometime use of genital talc (HR_{rb} 1.18, 95% CI 0.83 to 1.69) and use for one decade only (HR_{rb} 1.17, 95% CI 0.84 to 1.62) was also positively associated with an increased risk of ovarian cancer although the estimates did not reach statistical significance.

There was a statistically significant increased risk of ovarian cancer for ever user's vs never users of genital talc in the 20's as well as the 30's in both analysis that accounted for contradictory data correction and multiple imputation, as well as correction for recall bias.

It is notable that of that 15 out of the 18 analyses (**Table 3**) which examined the risk of ovarian cancer with genital talc use across different scenarios showed evidence of showed evidence of a positive association, of which 12 were statistically significant. Only three analyses for ever user's vs never users during their teenage years, or exposure year before enrollment showed a point estimate below 1. Similarly, among 19 different scenarios in multiple imputation models with contradictory data corrections and corrections for recall bias, 17 analyses reported a positive association between genital talc use and ovarian cancer, of which 13 were statistically significant (**Table A1**). The only two analyses which reported a HR_{rb} of < 1 were the analyses in which either 75% or 90% of talc users were assigned to be non-users. Such a large magnitude of recall bias is highly implausible.

The results on ever genital talc use and ovarian cancer were statistically significantly elevated when the analysis was limited to medically confirmed ovarian cases in multiple imputation models with contradictory data corrections ($n=226$ cases; HR 1.89, 95% CI 1.37 to 2.62), as well as models which additionally corrected for recall bias (HR_{rb} 1.46, 95% CI 1.06 to 2.02) as shown in **Table 4**. There were no differences in the increased risk of ovarian cancer associated with genital talc use by subtypes of ovarian cancer also shown in **Table 4**. Genital talc use was associated with a statistically significant increased risk of serous ovarian cancer in both multiple imputation models with contradictory data corrections ($n=126$ cases; HR 2.12, 95% CI 1.38 to 3.26) and well as models which additionally corrected for recall bias (HR_{rb} 1.62, 95% CI 1.06 to 2.48). The HR s for an increased risk for non-serous ovarian cancer were also statistically significantly elevated in in multiple imputation models with contradictory data corrections ($n=100$ cases; HR 1.64, 95% CI 1.02 to 2.65), and associated with a positively increased risk of non-serous ovarian cancer in models which additionally corrected for recall bias (HR_{rb} 1.29, 95% CI 0.79 to 2.09), but did not reach statistical significance in this analysis because of limited statistical power due to the small number of cases, a point noted by the editorial.²

The analysis which considered patency and genital talc use consistently reported a stronger statistically significant increased risk of ovarian cancer with genital talc use in both multiple imputation models with contradictory data corrections ($n=148$ cases, HR 1.83, 95% CI 1.36 to 2.46) and models which additionally corrected for recall bias (HR_{rb} 1.55, 95% CI 1.14 to 2.09) as shown in Table A3.

Douching was also not strongly associated with any of the outcomes on uterine cancer, breast cancer and ovarian cancer except for a positive association with ovarian cancer with frequent douching and douching during a woman's 20s and 30s. In contrast, the HR s for genital talc use and ovarian cancer remained statistically significantly elevated even after accounting for co-exposure with douching (HR 1.40, 95% CI 1.04 to 1.90)

The study noted that *"some talc may have been contaminated with asbestos, or other potentially harmful chemicals such as phthalates or parabens."*^{6,7}

The strengths of this study include the inclusion of additional ovarian cancer cases and follow up time with updated detailed data on prevalence of genital talc use and use during specific decades to facilitate the conduct of well-established advanced epidemiologic methods above.² As a result of the detailed data on exposure, it was able to address some of the major biases of prior cohort studies in measurement of exposure. The detailed follow up questionnaire allowed for adjustment for exposure misclassification and examining the influence of recall bias, and the analysis which accounted for both showed a statistically significant increased risk of ovarian cancer with genital talc use. This study established the presence of a dose-response effect for genital talc use and ovarian cancer with positive tests for trend by both frequency of use and duration of long-term use. This study also allowed the identification of a critical window of risk for increased ovarian cancer risk associated with genital talc use during the 20's and 30's.

There are some potential limitations to this study. Despite the addition of some ovarian cancer cases, the analysis was insufficiently powered to examine ovarian cancer by histologic subtypes (except for serous ovarian cancer) although there was no difference in increased risk by histologic subtype.

There is some potential for recall bias because the detailed fourth follow up questionnaire was used after some individuals had been diagnosed with ovarian cancer. However, it is important to consider not only whether such bias exists, and if so the magnitude of such bias, and whether it is differential or non-differential as these may have different implications for the exposure outcome relationship. Whereas non-differential recall bias usually biases estimate towards the null, depending on the context, differential recall can bias towards or away from the null. There is the potential for non-differential recall bias if both ovarian cancer cases and non-cases had an equally inaccurate recollection of genital talc exposure occurring decades ago since the questionnaire was implemented in 2017-2019 among participants enrolled in 2003-2009. Recall bias was likely minimal because of several reasons. 1) This was minimized by using a more comprehensive assessment in the detailed follow-up questionnaire. 2) Secondly, as the editorialists note, O'Brien et al. 2024 reported that even with a large degree of exposure misclassification there was persistent and significantly increased risk of ovarian cancer with genital talc use highlighting that recall bias cannot fully explain this result.² The editorialists similarly noted that "*even with misreporting of exposure (i.e., genital powder use) in half the cases, a significant increase in ovarian cancer risk is still observed, adding support to the plausibility of a true association between genital powder use and ovarian cancer risk.*"² 3) Thirdly, additional analysis limited to person-time accrued after the follow up questionnaire, not subject to any recall bias, also reported a positive association with genital talc use and ovarian cancer (HR 1.84, 95 % CI 0.90 to 3.77) similar to the overall analysis. 4) Finally, genital talc use was specifically associated only with an increased risk of ovarian cancer and not associated with uterine cancer, another gynecologic cancer, which makes recall bias an unlikely explanation of these findings, a point noted by the editorialists.² This finding of specificity to an increased risk of ovarian cancer, rather than another gynecologic cancer, with talc use is highly notable. If differential recall bias was truly operational, one would have also seen an increased risk with both gynecologic cancers which are likely to be indistinguishable to the general population.²

Although there were several strengths to the recall bias analysis, it may have also introduced some potential biases especially when compared to multiple imputation models with contradictory data corrections which they considered their best estimate. The final multiple imputation models with contradictory data corrections and correction for recall bias that evaluated the risk of ovarian cancer with genital talc use assigned 25% of infrequent and short-term user to be non-users as opposed to only 10% of non-case, non-users to be short term infrequent users biasing estimates towards the null. This bias is operational in 8 of the 9 statistical models in Table 3 (except for ever vs never use in the year before baseline) and all four statistical models in Table 4. This bias is further amplified in statistical models that

are already underpowered to begin with because of the small number of cases (e.g., non-serous ovarian cancer) attenuating HRs to the null even further.

Another potential limitation is that women who died with ovarian cancer could not complete the questionnaire. However, any such reduction in the number of ovarian cancer cases would likely bias estimates towards the null

Although the authors adjusted for several well-established confounders, unmeasured confounding is always possible in an epidemiologic study, which is another limitation. However, one can measure the potential for unmeasured confounding using E-values.^{8,9} The E-value as defined by Vanderweele and Ding “*is the minimum strength of association, on the risk ratio scale, that an unmeasured confounder would need to have with both the treatment and the outcome to fully explain away a specific treatment-outcome association, conditional on the measured covariates. A large E-value implies that considerable unmeasured confounding would be needed to explain away an effect estimate. A small E-value implies little unmeasured confounding would be needed to explain away an effect estimate.*

“^{8,9} They further state that if reporting of E-values would become standard practice “*the ability of the scientific community to assess evidence from observational studies would improve considerably, and ultimately, science would be strengthened.*”⁹

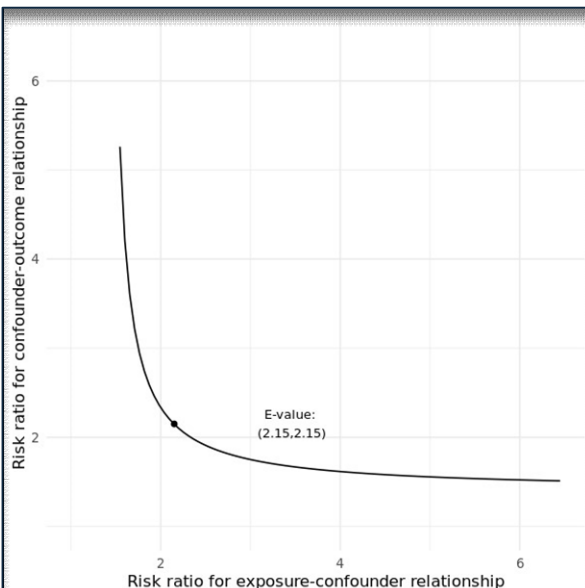


Figure 2. E-values for analysis for multiple imputation models corrected for contradictory data and recall bias

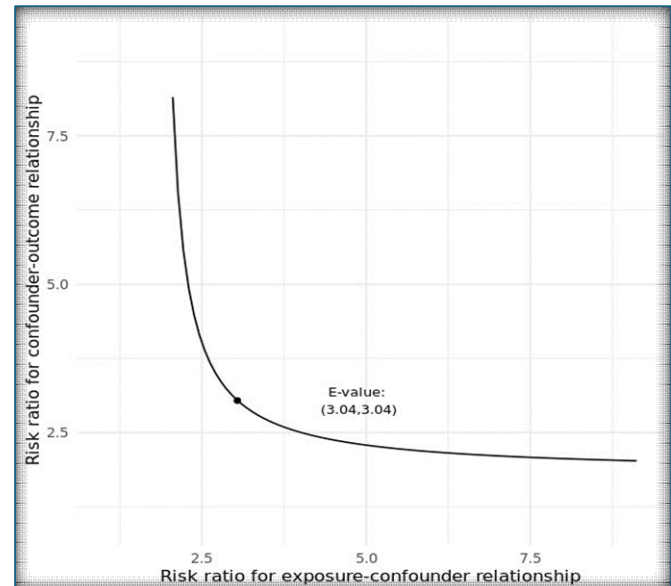


Figure 1. E-values for analysis for multiple imputation models corrected for contradictory data

I estimated the E-values using the HRs (HR 1.82, 95% CI 1.32 to 2.43) provided in the multiple imputation models corrected for contradictory data assuming an outcome prevalence of < 15% for a rare outcome such as ovarian cancer using well established methods of E-value estimation recommended in observational studies.^{8,9} I used their calculator available at <https://www.evalue-calculator.com/evalue/>.^{8,9} These resulted in the E-value for point estimate: 3.04 and for confidence interval: 2.06 (**Figure 1**).^{8,9} I also estimated the E-value for the multiple imputation models corrected for contradictory data and recall bias (HR 1.40, 95% CI 1.04 to 1.89) assuming a reasonable outcome prevalence of < 15% for ovarian cancer. The E-value point estimate is 2.15 and for confidence interval is 1.24 (**Figure 2**). Given that the analysis already adjusted for all major confounders for the talc-ovarian cancer relationship including race/ethnicity, education, BMI, age at menarche, birth control use, parity, menopausal status, hormone therapy, smoking status, alcohol use, and geographic region, missing data, as well as accounted for

misclassification of exposure and recall bias, such large E values indicate that unmeasured confounding is an unlikely explanation of the increased risk of ovarian cancer associated with genital talc exposure.

The editorialists rightly call for primary care providers and obstetricians and gynecologists to routinely discuss this modifiable risk factor for ovarian cancer to effectively induce behavior change.² In an accompanying press release by American Society of Clinical Oncology, the authors noted that “*the study provides more reliable evidence that supports a potential association between long term use and frequent genital talc use and ovarian cancer.*”¹⁰ Despite providing evidence of a strong, reliable and consistently positive association between genital talc use and ovarian cancer with strong evidence of a dose response effect, the authors acknowledge that their study does not pinpoint a specific cause or mechanism with still some potential for uncertainty around recall bias, and that these results do not establish causality.¹ However, it would be premature to draw inference on causality or pinpoint a specific mechanism from any single study alone, as a single study can only provide evidence either in support or evidence against a causal association between genital talc use and ovarian cancer. Any inference on causality needs to first consider, not only the results of this study, but these results in the context of an existing, mature evidence base comprised of numerous case control studies, cohort studies and meta-analyses that have consistently shown positive findings of a strong and reliable association between genital talc use and ovarian cancer. A careful examination of the Bradford Hills viewpoints on cumulative body of evidence is needed to draw inferences on causality.

After considering the strengths and weakness of their study, including the potential for chance, bias and measured and unmeasured confounding, I incorporated the results into my consideration of the Bradford Hill viewpoints of *strength of association, consistency, specificity, biological gradient, plausibility, and coherence*. (Pg 19 to 22 of my supplemental report).

This study provides evidence of a statistically significant, precise, and consistent increased risk of ovarian cancer associated with genital talc use and further supports the viewpoints on *strength of association*. The point estimate on the magnitude of risk is in the order of 82% for their best estimate (HR 1.82, 95% CI 1.36 to 2.43) after adjusting for potential misclassification and multiple imputation. After adjusting for recall bias the estimates are mildly attenuated (HR_{rb} 1.40, 1.04 to 1.89) but a significantly increased risk in the order of a 40% for ever use of genital talc and ovarian cancer was still noted. The strength of association exceeds a two-fold risk for long term users in all analyses, whereas range from a 81% increased risk to 99% increased risk for frequent users, all of which provide evidence of a strong association.

The study provides further support for consistency of an increased risk between genital talc use and the development of ovarian cancer. In the study majority (> 90%) of the analysis accounting for several biases provided evidence of a positive association between genital talc use and ovarian cancer (Table 3). Across the entire body of evidence the confidence intervals here overlap with that from case-control studies, cohort studies, pooled analysis of cohorts and meta-analysis proving further evidence of consistency.¹¹⁻¹³ Both the authors and editorialists agree that the study provides evidence of a positive and consistent association.^{1,2} The author state, “*our findings of a positive association between genital talc use and ovarian cancer are consistent with previous studies.*”¹ The editorialists concur that “*these effect estimates are in range with previous studies.*”² Further evidence of consistency is shown by the fact that the increased risk of ovarian cancer associated with talc use was seen during the critical time windows of age 20-39 years. This evidence of a consistency of an increased risk is also highlighted by the authors,¹ “*Results from the present analysis suggest age 20-39 years may be a window of susceptibility, which is consistent with previous studies that considered age of use.*”¹⁴⁻¹⁶ Further there were no difference in increased risk by histologic subtypes, despite statistically underpowered analysis for non-serous ovarian cancer providing

evidence on the consistency viewpoint. The authors note “ *We did not observe difference in HRs by subtypes*”.¹

There is evidence of a biological gradient or a monotonic dose-response effect with an increased risk of ovarian cancer by both frequency and duration of genital talc use, accompanied by statistically significant tests for trend in both analyses. Long term users of genital talc had a more than doubling in the risk of ovarian cancer. The presence of such a strong monotonic dose-response effect, accompanied by statistically significant positive tests for trend, and the large magnitude of dose-response provides strong support for the Bradford Hill viewpoint on biological gradient.

The authors state that talc may contain additional harmful chemicals beyond asbestos which provide further evidence in support of a biologically plausible mechanism of genital talc induced ovarian cancer. The results show that the risk of ovarian cancer was highest in the 20’s and 30’s and provide further support of plausible mechanisms via talc induced migration and inflammation. This is the critical window where there is the potential for increased use of genital talc before hysterectomies and tubal ligation are performed.¹

The study finding that the risk of ovarian cancer was highest in the 20’s and 30’s supports the viewpoint on coherence as these do not conflict with the generally known facts and biology of ovarian cancer. This is the time window where sexual activity may result in increased use of genital talc and chronic irritation of the ovaries and fallopian tube and contribute to carcinogenesis.¹ The ability to update data on exposure in this cohort study, which in general had limited ability to assess exposure as compared to case controls,^{3,4} also support the viewpoint on coherence. The increased risk of ovarian cancer with genital talc use seen in this study is coherent with the results of numerous case control studies with more detailed data on exposure.

In summary, The O’Brien 2024 study strongly supports and reaffirms my opinion that genital use of talcum powder products can cause ovarian cancer as stated in my 2018 Report and 2023 Addendum.

References.

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EXHIBIT A

Sonal Singh MD MPH FACP

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Education

MPH, Bloomberg School of Public Health, Johns Hopkins University Baltimore, MD	6/2005 to 5/2008
Internal Medicine Residency, Unity Health System, affiliate University of Rochester Sch of Medicine and Dentistry, Rochester, NY	7/2002 to 6/2005
MD, Patna Medical College, Patna, India	12/91 to 05/1999

Academic Appointments

Associate Professor, Department of Family Medicine & Comm Health Department of Medicine, University of Massachusetts Medical School	10/2016 to date
Assistant Professor, Dept of Medicine, Johns Hopkins Univ SOM	7/2009 to 9/2016
Assistant Professor, Center for Public Health, and Human Rights Bloomberg School of Public Health, JHU	7/2009 to 9/2016
Assistant Professor, Department of Medicine, Wake Forest University	7/2007 to 6/2009
Instructor, Department of Medicine, Wake Forest University	7/2005 to 06/2007

Employment History

Associate Professor, Department of Fam Medicine & Comm Hlth UMass Chan Medical School Role: Clinician- Investigator	10/2016-present
Associate Professor, Department of Quantitative Health Sciences UMass Chan Medical School Role: Clinician- Investigator	10/2018-present
Associate Professor, Department of Medicine, Division of Hlth System Sciences UMass Chan Medical School Role: Clinician- Investigator	10/2022-present
Assistant Professor, Dept of Medicine, Johns Hopkins University. Role: Clinician- Investigator	7/2009 to 9/2016
Assistant Professor, Department of Medicine, Wake Forest University	7/2007 to 6/2009

Role: Clinician- Educator

Instructor, Department of Medicine, Wake Forest University	7/2005 to 6/2007
Role: Clinician- Educator	

Residency (Medicine) Unity Healthy System, University of Rochester, Rochester, NY	Role: PGY 1,
PGYII and PGY III Internal Medicine Resident	7/2002 to 6/2005

Research Associate, Clinical Pharmacology, Ohio State University	3/2001 to 6/2002
Role: Research assistant in clinical trials	

Voluntary Research Associate, Clinical Pharmacology, Ohio State	8/2000 to 2/2001
Role: Research assistant in clinical trials	

USMLE STEP 1, II, III and Clinical Skills Exam Preparation	2/2000 to 7/2000
Role; Medical student	

Resident, Medicine, Patna Medical College, Patna, Bihar, India	2/1998 to 1/2000
Role: Junior Resident in Medicine	

Compulsory rotatory internship, Patna Medical College, Patna, India	12/1997 to 12/1998
Role: Fulfilling requirements for completion of medical degree in India	

Certification and Licensure

Diplomate, American Board of Internal Medicine	8/2005-12/2025
Massachusetts Board of Physicians	8/6/2016-8/6/2023
Physicians and Surgeons of Maryland (Inactive)	2009-2017
North Carolina Medical Board (Inactive)	2005-2009
Basic Life Support (Active)	2016-2023

Professional Memberships and Activities

Massachusetts Medical Society	2017-current
American College of Physicians	2003-current
International Society of Pharmacoepidemiology	2011-current
Society of General Internal Medicine	2003-2016
International Society of Pharmacoeconomic Outcomes Research	2016-2017
Academy Health	2013
Global Health Council	2006-2010
Association of Physicians of Indian Origin (AAPI)	2020-current

Honors and Awards

- 2022 : Dave Sackett Clinical Trial of the Year Award, Society for Clinical Trials, Member, Data Safety Monitoring Committee-TOGETHER trial

- 2019: Elected to the Fellow of the American College of Physicians
- 2017 : Elected, American College of Chest Physicians CHEST Expert Cough Panel
- 2016: Finalist W. Leigh Thompson Excellence in Research: Johns Hopkins University SOM
- 2013 : Visiting Professor, Department of Medicine, University of Alabama, Alabama, USA
- 2013 : Appointee World Health Organization, International Agency for Research on Cancer Evaluation of Drugs and Herbal Products, Lyon, France.
- 2013 : Awardee, 29th International Society of Pharmacoepidemiology, Montreal, IIIrd Best Abstract, Trainee
- 2011 : Awardee, Bruce P Squires Award for the Best Research Paper, Canadian Medical Association Journal
- 2011: Awardee, Society of General Internal Medicine Clinical Investigator (Mid-Atlantic)
- 2010 : Awardee, Scholars Abstract Award, Society for Clinical and Translational Sciences
- 2009 : Awardee, NIH/KL2 Award and Junior Research Scholar, Johns Hopkins Clinical Research Program, Johns Hopkins School of Medicine
- 2010 : Elected, Delta Omega Honorary Public Health Society, Johns Hopkins University
- 2008 : Elected Master Teacher Award, Wake Forest University School of Medicine
- 2006 : Awardee, Tinsley R Harrison Faculty Teaching Award Wake Forest University SOM
- 2007 : Awardee, Tinsley R Harrison Faculty Teaching Award Wake Forest University SOM
- 2005 : Senior-Resident Scholarship award, Unity Health System, University of Rochester SOM& Dentistry
- 2005 : American College of Physicians Health and Public Policy Scholarship, NY

Committee Assignments & Administrative Service

Public Policy Committee, International Society of Pharmacoepidemiology	2020-2021
Population Health & Pharmacy Collaborative Committee, UMASS	2019-2020
American College of Physicians, Massachusetts, Health Policy Committee	2018-2019
Chairs Advisory Council, Department of Fam Medicine & Comm Hlth	2016-2018
American College of Chest Physicians, Cough Guideline Expert Panel	2017- current
Associate faculty, Welch Ctr for Prevention, Epi & Clin Research, JHU	2015-2016
Associate-Director, Center for Drug Safety and Effectiveness, JHU	2013-2016
Affiliate faculty, Center for Hlth Services and Outcomes Research, JHSPH	2012-2016
WHO, International Agency of Research on Cancer (IARC) Working group	2013
Preferred Items for Reporting of Systematic Reviews and Meta-analysis of harms Working Group	
Alberta Canada.	2012-2012
Health & Human Rights Working Group, JHU Center for Aids Research	2012
Core faculty, Center for Public Health and Human Rights, Johns Hopkins Bloomberg School of Public Health	2009-2016
Core faculty, Evidence-Based Practice Center, JHU	2009-2016
Medical Director, Outpatient Clinic, WFUSOM	7/2005-6/2009

Teaching Activities

Classroom

Epidemiology	2020-2022
Role: Facilitator course in Clinical Epidemiology for Medical Students at University of Massachusetts Medical School	
Comparative effectiveness research (2 credits), Johns Hopkins Medicine	2015-2016
Role: Developed course in CER for MD and MD/PhD trainees in the CTSA	
Health and Human Rights, Johns Hopkins Bloomberg School of Public Health	2011-2015
Role: Annual lecture in the course for MPH students	
Health Economic, Johns Hopkins Bloomberg School of Public Health	2013
Role: Annual lecture in the course for master's students	
Pharmacoepidemiology, Johns Hopkins Bloomberg School of Public Health	2011-2015
Role: Annual lecture in the course for master's and Doctoral students	
Evidence-based Medicine, Johns Hopkins University School of Medicine	2012
Role: Course facilitator	
Intro to Clinical Investigation, Johns Hopkins University School of Medicine	2012
Role: Annual lecture in the course	
Clinical Epidemiology, Johns Hopkins Bloomberg School of Public Health,	2010-2014
Role: Annual lecture in the course	
Patient Physician and Society, Johns Hopkins University School of Medicine	2009
Role: Course facilitator	
<u>Clinical Teaching</u>	
Outpatient medicine	2016-current
Role: Precepting IIIrd year medical students in clinic at University of Massachusetts Medical School	
Evidence Based Medicine	2012-2014
Role: Developed a novel course to teach Evidence based Medicine to Osler medical residents at Johns Hopkins University School of Medicine	
Outpatient medicine	2005-2009
Role: Precepting residents in clinic at Wake Forest University	
Inpatient Medicine	2005-2009
Role: Precepting internal medicine residents at Wake Forest University	

Mentoring

UMass Chan Medical School		Project	Current Position and Institution	Training Period
Faculty				
Idanis Berriosmorales MD	Mentor	SR of SDM in MS	Asst. Professor of Neurology, UMass Chan Medical School	2019-2021
Mayuko Itofukunaga, MD	Mentor	Systematic review of decision aids for lung cancer screening	Assistant Professor-Pulmonary Medicine UMass Chan Medical School	2018-2020
Ayobami Akenroy MD	Mentor	Pharmacovigilance study of switching biologics in asthma	Assistant Professor-Harvard Medical School	2022
Trainees				
Jessica Kloppenburg	Scholarly activity	SR of SARS-COV-19 and Maternal-fetal outcomes	MD/PhD Student UMass Chan Medical School	2020-
Nathaniel, Erskine MD, PhD (student)	Scholarly activity	SR of herpes zoster and cardiovascular disease	MD/PhD Student UMass Chan Medical School	2017-18
Richeek Pradhan MS	Scholarly Activity	Comparison of data on Adverse events	Post-doctoral Fellow, Harvard School of Public Health	2017-18

Johns Hopkins University**Faculty**

Hsien-Yen Chang PhD	Mentor	Pharmacoepidemiologic studies	Director, Real World Research at Janssen LLC	2011-15
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Trainees at Johns Hopkins Bloomberg School of Public Health

Omar Mansour	Scholarly activity	SGLT2inhibitors and cardiovascular outcomes	Masters' student, JHSPH	2018
Geetha Iyer, MD	Mentor	Multiple Pharmacoepidemiologic studies	Post-doctoral fellow, Harvard School of Public Health	2015-16

Sathiya Priya Marimuthu, MPH	Mentor	Generic drugs and patient-oriented outcomes	Senior Clinical Trial Physician at Bristol Myers Squibb	2015-16
Yohalakshmi Chelludari, MD, MPH	RA Scholarly activity	Review of varenicline	Internist, Salem, Oregon	2013
Hasan Shihab, MD, MPH	Scholarly activity	Review of GLP-based therapies	Attending Physician OSF HealthCare, IL	2013-14
Joshua Sclar, MD, MPH	Scholarly activity	Systematic review of attacks on health workers	Chief Medical Officer, Avesis	2013
Crystal Ng, MPH	Scholarly activity	Human Rights measures	MPH Student, JHSPH	2013
Ekta Agarwal, MPH	Capstone	Safety of novel anticoagulants	Senior Director/ Evidence Generation Lead/ Pfizer	2013
Meijia Zhou, MHS	Scholarly activity	Adherence to novel anticoagulants	Manager, Real-World Data Analytics & Research, Medical Devices Epidemiology, Johnson and Johnson	2013
Kaitlin Hayman, MD	Capstone	SR of the impact of disasters On CVD outcomes	MPH student, JHSPH	2013
Wenze Tang, MPH	Scholarly activity	SCCS analysis of GIB bleeding with dabigatran	Manager, Janssen Pharmaceutical Companies of Johnson & Johnson	2013
Shabana Walia MD	Scholarly activity	SR of CVD among refugees and displaced	ER physician, UT Houston	2016-18
Wake Forest University SOM				
Aman Amin, MD	Scholarly activity	SR of Inhaled corticosteroids and pneumonia	Practicing internist, NC	2007-09
Apurva Trivedi, MD	Scholarly activity	Systematic Review of SSRIs and bleeding	Gastroenterologist	2007-09
External institutions				
Tonya Breaux-Shropshire PhD, MPH	Scholarly activity	Systematic review of ambulatory BP	Clinical Scientist in Hypertension Research at University of Alabama at Birmingham	2015
Abhay Kumar, MD	Resident Scholarly activity	Wernicke encephalopathy after gastric bypass: systematic review	Associate Professor of Neurosurgery, UT Houston	2007

Submitted Grants

NIA (NOT-AG-23-032) (PI : Gurwitz) 09/22-04/2024
Developing Processes and Tools to Assess the Safety of Anti-amyloid therapies for Alzheimer's Disease using Real World Data.
The aim is to develop tools to assess the safety of anti-amyloid therapies for Alzheimer's Disease using Real World Data
Role (Co-investigator 10% FTE)

Current Grants

Developing and applying a framework to evaluate and conduct algorithm validation studies for MACE 11/2023- 10/2024.
Reagan Udall Foundation for the FDA \$ 130,000
The aim is to develop the Algorithm Certainty Tool (ACE-IT) tool to appraise whether real world algorithms are fit for purpose for regulatory surveillance with a focus on major adverse cardiovascular outcomes

1 R01 MD016883-01 (PI-Fisher) 5/17/21-02/29/2024
NIMHHD \$702,150
Trusted messengers: Supporting physicians in promoting COVID-19 vaccination.
The major goals of this project are: (1) To refine and adapt tools to support effective PCP recommendations for COVID-19 vaccination and information dissemination by PCPs and community organizations to vulnerable patients; (2) To implement and assess the impact of the intervention on COVID-19 vaccine uptake among initially unvaccinated patients and (3) To evaluate the intervention according to the REAIM framework, incorporating the perspectives of patients, primary care providers, and clinic leaders.
Role: Co-Investigator (15%)

NIH 33AG069794 9 (PI-Gurwitz) 09/2021-08/2025
Developing a Program to Educate and Sensitize Caregivers to Reduce the Inappropriate Prescription Burden in Elderly with Alzheimer's Disease Study (D-PRESCRIBE-AD) 1,077,838 (FY23)
The aim is to conduct a large, cluster randomized, pragmatic trial to evaluate a health plan-based intervention leveraging the NIH Collaboratory's Distributed Research Network, which uses the Food and Drug Administration (FDA) Sentinel Initiative infrastructure.
Role: Co-investigator (20%)

Completed Grants and Contracts

NIA 3R33AG057806-05S1 09/22-04/2024
Preparing for what is next with aducanumab in Real World Settings (PI-Gurwitz)
NIA \$ 434,125
The aim is to develop a state-of-the-art master protocol to conduct a real-world evaluation of the novel monoclonal antibodies for dementia.
Role (Co-investigator 20% FTE)

Developing and applying a framework to evaluate and conduct algorithm validation studies for MACE 03/2021—5/2022.
Reagan Udall Foundation for the FDA \$ 105,462
The aim is to develop the Algorithm Certainty Tool (ACE-IT) tool to appraise whether real world algorithms are fit for purpose for regulatory surveillance with a focus on major adverse cardiovascular outcomes.
Role : Principal Investigator (15%)

NIH R61AG069794-01(PI-Gurwitz)	09/2020-08/2021
Developing a Program to Educate and Sensitize Caregivers to Reduce the Inappropriate Prescription Burden in Elderly with Alzheimer's Disease Study (D-PRESCRIBE-AD)	
The aim is to conduct a pilot study to assess the feasibility and acceptability of a large, cluster randomized, pragmatic trial to evaluate a health plan-based intervention leveraging the NIH Collaboratory's Distributed Research Network, which uses the Food and Drug Administration (FDA) Sentinel Initiative infrastructure.	
Role: Co-investigator- 15%	
PCORI HIS-1608-35689-IC (PI-Ming Tai-Seale)	2/2016- 3/2021
Improving Patient-Centered Communication in Primary Care: A Cluster Randomized Controlled Trial of the Comparative Effectiveness of Three Interventions	
The aim is to compare three interventions to improve patient communication in primary care.	
Role: Co-investigator (10%)	
(PI Jerry Gurwitz)	08/2018- 08/2020
NIH/NIA-1 R56 AG061813-01	
Project Title: Controlling and Stopping Cascades leading to Adverse Drug Effects Study in Alzheimer's Disease(CASCADES-AD)	
Role: co-investigator.	
The aim is to develop interventions to prevent prescribing cascades among those with Alzheimer's related Dementia (ADRD)	
Death Data Exploration	08/01/17- 03/02/18
Task Order Number: HHSF22301012T	
Efforts to Develop the Sentinel Initiative HHSF223200910006I.	
Role (Project Lead)	
Effect of Therapeutic Class on Generic Drug Substitutions.	2014-2016
U01FD005267-01 (PI, Jodi Segal)	
FDA	\$ 349,480
Role: Co-Investigator	
Comparative effectiveness Research & The Cochrane Eyes and Vision Group	2013-16
U01 EY020522 (PI, Kay Dickersin)	
NIH/NEI	\$ 825,397
Role: Co-Investigator	
Systematic review of gabapentin for neuropathic pain using multiple data sources	2015-16
(PI, Caleb Alexander)	
FDA Center of Excellence in Regulatory Science	
Role: Co-Investigator (20% effort)	
Integrating multiple data sources for meta-analysis to improve patient-centered outcomes.	
research	2014-2016
(PI- Dickersin)	
PCORI (ME-1303-5785)	\$698,174
Role: Advisor (2% effort)	
Development of a scale for human rights violations.	2013-2014
(PI, Chaisson & Beyrer)	
NIH Johns Hopkins Center for AIDS Research	\$ 18,873
Role: Pilot Awardee	

Comparative effectiveness review of therapeutic options for obesity in the Medicare population. Johns Hopkins Evidence Based Practice Center. PI (Eric Bass) AHRQ Role: Co- Investigator (20% effort)	2013-2014 \$125,000
Center for Excellence in Comparative Effectiveness Education PHRMA Foundation (PI Jodi Segal) Role: Co-investigator (5% effort)	2012-2013 \$250,000
A multi criteria decision analysis to assist with regulatory decisions around benefit and risk. Partnership in Applied Comparative Effectiveness Science: PI (PI, Jodi Segal). FDA Role: Project Principal Investigator (25% effort)	2010-2013 \$3,509,657
Combination therapy vs. intensification of statin monotherapy: An update. PI (E. Bass- P.I of EPC.) AHRQ Role: Advisor (5% effort)	2012-2013
Troponin cardiac marker during renal impairment. (E. Bass- P.I of EPC.) Agency for Health Care Quality and Research Role: Advisor (5% effort)	2012-2013
To develop an instrument for attacks on health workers. PI (Len Rubenstein) US Institute of Peace Role: Co-investigator (10% effort)	2012-2013
To develop an instrument for attacks on health workers. PI (Len Rubenstein) McArthur Foundation Role: Co-investigator (15% effort)	2012-2013 \$434,782
To conduct a benefit and harm assessment of <i>roflumilast</i> in COPD. Johns Hopkins ICTR Role: Co-investigator (5% effort)	2012-2013
To develop a China-JHU consultation for civil society public health professionals. Open Society Foundation Role: PI (20% effort). Proposal for a public health training program.	2012 \$49,534
PACER. PI (Rothman) Google-Flu Role: Coinvestigator (5%) Systematic reviewer and meta-analysis expert.	2012
Methods for Balancing Benefits and Harms in Systematic Reviews Johns Hopkins Evidence Based Practice Center. (PI, Bass) AHRQ Role: Project Task Leader and co-Investigator (10% effort)	2011-2012 \$188,871

Comparative effectiveness review of Meditation Programs for Stress and Wellbeing Johns Hopkins Evidence Based Practice Center. (PI, Bass) AHRQ Role: Project Task Leader and co-Investigator (15% effort)	2011-2012 \$375,666
Comparative effectiveness review of prevention of VTE in special populations Johns Hopkins Evidence Based Practice Center. (PI, Bass) AHRQ Role: Project Principal Investigator (20% effort)	2011-2012 \$375,666
To prevent and respond to gender-based violence (GBV) in refugee and conflict-affected populations. (PI, Vu & Rubenstein) Role: Co-investigator (10% effort)	2010-2011 \$293,946
Comparative effectiveness review of oral hypoglycemic medications Johns Hopkins Evidence Based Practice Center. (PI, Bass) AHRQ Role: Co- Investigator (0% effort)	2009-2010 \$125,000
Johns Hopkins Clinical Research Junior Faculty Award. NIH-KL2 ICTR Role: Recipient (75% salary support)	2009-2012
Measuring exposure to human rights violations among men who have sex with men. (PI, Mullany). Center for Global Health Johns Hopkins Role: Co-investigator (0% effort).	2009-2010 \$50,000.00
Research ethics for conducting research in vulnerable populations and unstable settings. (PI, Mills) CIHR Role: Co-investigator (10% effort).	2007-2009 \$99, 887.00

Editorial work

Editor-in-chief and founder

BMC Conflict and Health 2017-2012

Editorial Board Membership

Frontiers in Drug Safety	2022-current
Frontiers in Primary Care and Family Medicine	2021 current
Evidence Based Medicine (BMJ Group of Journals)	2017- 2023
Drug Safety	2008-2016
American College of Physicians	PIER

Grant Review

Extramural Grant Review for US Federal Agencies	
<u>Center for Disease Control</u> . Special Emphasis Panel Effective Community Conversations for Influenza and COVID-19 Vaccine Uptake May 2 2023	
<u>Patient Centered Outcomes Research Institute</u> - Rare Disease Research Panel, November 20, 2020	
International Agencies	
Medical Research foundation of New Zealand	
Medical Research Council of South Africa	
Catalina Health Technology Assessment, Spain	
Diabetes, UK	
Intramural	
Johns Hopkins Center for Public Health and Human Rights Junior Faculty Research Grants	
Johns Hopkins Medicine Research Council Synergy Awards	
Johns Hopkins Institute for Clinical and Translational Research Awards	

Data Safety Monitoring Board

Repurposed Approved Therapies for Outpatient Treatment of Patients with Early-Onset COVID-19 and Mild Symptoms (www.togethertrial.com) David Sacket Clinical Trial of the Year Award 03/2021

Peer Review

<i>Acta Diabetologica</i>
<i>American Heart Journal</i>
<i>American Journal of Addictions</i>
<i>American Journal of Cardiovascular Drugs</i>
<i>American Journal of Managed Care</i>
<i>American Journal of Psychiatry</i>
<i>American Journal of Tropical Medicine and Hygiene</i>
<i>Annals of Internal Medicine</i>
<i>Annals of Medicine</i>
<i>Australian Medical Journal</i>
<i>BMJ</i>
<i>BMC Clinical Pharmacology</i>
<i>British Journal of Clinical Pharmacology</i>
<i>Bulletin of the World Health Organization</i>
<i>Chest</i>
<i>Circulation</i>
<i>Canadian Medical Association Journal</i>
<i>Clinical Pharmacology and Therapeutics</i>
<i>Clinical Trials</i>
<i>Cardiovascular Drugs & Therapy</i>
<i>Cochrane Collaboration</i>
<i>Disasters</i>
<i>Diabetologia</i>
<i>Drug and Alcohol Dependence</i>
<i>Diabetes Obesity and Metabolism</i>
<i>Drug Safety</i>
<i>Epidemiology</i>
<i>European Journal of Neurology</i>
<i>European Journal of Pharmacology</i>
<i>European Respiratory Journal</i>
<i>Expert Opinion in Drug Safety</i>
<i>Global Public Health</i>
<i>Health Policy</i>
<i>International Journal of Clinical practice</i>
<i>International Journal of Epi</i>
<i>International Journal of Obesity</i>
<i>Journal of the American College of Cardiology</i>
<i>Journal of the American Medical Association > 25 articles</i>
<i>Journal of the American Medical Association-Internal Medicine</i>
<i>JAMA-Network Open</i>
<i>Journal of Cardiac Failure</i>
<i>Journal of Medical Case Reports</i>
<i>Journal of the Pancreas</i>
<i>Journal of General Internal Medicine</i>
<i>Medscape General Medicine</i>
<i>Medical Journal of Australia</i>

<i>Nephrology Dialysis Transplantation</i>
<i>North Carolina Medical Journal</i>
<i>Nutrition, Metabolism & Cardiovascular Diseases</i>
<i>Open Forum for Infectious Disease</i>
<i>Pediatric Infectious Disease Journal</i>
<i>Pharmacoepidemiology & Drug Safety-Best Reviewer Award 2013</i>
<i>Public Library of Science Medicine</i>
<i>Primary Care Respiratory Journal</i>
<i>Pediatrics</i>
<i>Research Synthesis Methods</i>
<i>Respiratory Medicine</i>
<i>Respirology</i>
<i>Southern Medical Journal</i>
<i>The Lancet</i>
<i>Thorax</i>
<i>Tropical Medicine & International Health</i>

ABSTRACTS/PRESENTATIONS

National/International Oral Conference Presentation

1. Mazor KM, Fisher KA, Nguyen N, Fouayzi H, Crawford S, Singh S, Dong M, Wittenberg R. From vaccine hesitancy to vaccine acceptance: Who changes and why? Oral presentation at: The Health Care Systems Research Network; April 12-14, 2022; Pasadena, CA.
2. Risk of myocarditis associated with checkpoint inhibitors. 35th International Society of Pharmacoepidemiology, Annual Meeting, Philadelphia. Aug 26, 2019.
3. GLP-1-based therapies and risk of pancreatitis: A matched case-control study. 29th International Society of Pharmacoepidemiology, Annual Meeting, Montreal Convention Center, August 26. Montreal, Quebec, Canada.2013
4. GLP-1 based therapies and risk of pancreatitis. 36th SGIM Annual Meeting, Denver, Colorado. 2013
5. Risk of fractures with inhaled corticosteroids in COPD: Systematic review and meta-analysis of randomized controlled trials and observational studies, Society of General Internal Medicine, Minneapolis, Minnesota. 2011
6. Odds of fractures with inhaled corticosteroids in COPD: Systematic review and meta-analysis of clinical trials and observational studies, 27th International Society of Pharmacoepidemiology, Annual Meeting, Hyatt Regency August 24th. Chicago, Illinois. 2011

National/International Poster Presentation

1. Suad Khabbaha, Sarah Carder Dempsey, Aranka Anema, Sonal Singh, and Kristian Thorlund. Characterizing adverse events across 30,000 peer reviewed case report publications. Journal of Clinical Oncology 2023 41:16_suppl, e18858-e18858. Published online May 31 2023. 2023 ASCO Annual Meeting.
2. Suad Khabbaha, Sarah Carder Dempsey, Aranka Anema, Sonal Singh, and Kristian Thorlund. Is aggregate use of published case reports as a viable option for augmenting pharmacovigilance? An applied example of pembrolizumab-related adverse events in patients with non-small cell lung

- cancer receiving first-line treatment. Journal of Clinical Oncology 2023 41:16_suppl, e18840-e18840. Published online May 31 2023. 2023 ASCO Annual Meeting.
3. Sonal Singh, Julie Beyrer, Xiaofeng Zhou, Joel N Swerdel, Raymond A Harvey, Kenneth Hornbuckle, Leo Russo, Kanwal Ghauri, Ivan H Abi-Elias, Carla V Rodriguez-Watson. Development and Evaluation of the ALgorithm CErtainty Tool KIT (ACE-IT) to evaluate safety outcomes using electronic medical record and claims-based algorithms. 38th International Society of Pharmacoepidemiology, Annual Meeting, Copenhagen, Denmark. Aug 28, 2022.
 4. Thomas Moore, Sonal Singh. Challenges of Using Real-World Evidence for Regulatory Decisions: 4 Key Issues. 38th International Society of Pharmacoepidemiology, Annual Meeting, Copenhagen, Denmark. Aug 27, 2022.
 5. Sonal Singh. Noelle Cocoros, Kevin Haynes, Vinit Nair, Thomas Harkins, Paula Rochon, Richard Platt, Sybil Crawford, and Jerry Gurwitz. Population based estimates of prescribing cascades among older adults with Alzheimer's dementia. 36th International Society of Pharmacoepidemiology, Annual Meeting. September 16th 2020
 6. Sarah Bloomstone KA, Noelle Cocoros, Jerry Gurwitz, Kevin Haynes, Vinit Nair, Richard Platt, Paula Rochon, Sonal Singh, Kathleen M. Mazor. Prescribing Cascades in Patients With Alzheimer's Disease: Engaging Patients, Caregivers, Payers, and Providers. Abstracts from the 26th annual Health Care Systems Research Network Conference, April 8-10, 2020. J Patient Cent Res Rev. 2020;7:94.
 7. Diagnostic algorithms for cardiovascular death in administrative claims databases. A systematic review 2018. International Society of Pharmacoepidemiology, Prague, August 24, 2018.
 8. Risk of gastrointestinal bleeding among dabigatran users-a self-controlled case series analysis. Health Care Systems Research Network, San Diego, March 22, 2017.
 9. GLP-1 based therapies and risk of pancreatitis. Pancreatitis, Diabetes, and Pancreatic Cancer Workshop. NIH, Bethesda, Maryland. 2013
 10. Thiazolidinediones and risk of bladder cancer: A systematic review and meta-analysis. 36th SGIM Annual Meeting, Denver, Colorado. 2013
 11. Who is the patient's doctor? Primary care responsibility and co-management relationships among generalist and non-generalist physicians in the National Ambulatory Care Survey, 2002 SGIM 29th Annual Meeting, Los Angeles, California. 2006
 12. The educational value of case reports from the SGIM national meeting in the internal medicine clerkship. SGIM 29th Annual Meeting, Los Angeles, California. 2006
 13. Using iPod technology to create a self-guided clinic tour for resident orientation SGIM 29th Annual Meeting, Los Angeles, California. 2006
 14. Narcotic management in chronic non-malignant pain. A survey of residents' knowledge and attitudes. SGIM 29th Annual Meeting, Los Angeles, California. 2006
 15. Formulary conversion programs pose a significant risk to patients, SGIM 27th Annual Meeting, Chicago, Illinois. 2004

[Posters at local regional meetings](#)

Inhaled corticosteroids and the risk of fractures in COPD: A systematic review and meta-analysis. DOM Annual retreat, Johns Hopkins University 2011

[National/International Oral Presentations](#)

1. Development and Evaluation of the ALgorithm CErtainty Tool KIT (ACE-IT) to evaluate safety outcomes using electronic medical record and claims-based algorithm. International Society of Pharmacovigilance (ISoP) Journal Club. Webinar March 30 2023
2. Oral direct acting antivirals and the incidence or recurrence of hepatocellular carcinoma. NIH Collaboratory Grand Rounds. March 2, 2018
3. Resurgence of hepatocellular carcinoma in the era of oral direct acting antivirals. Cause or Consequence? Fundamentals of Biomedicine Seminar Series. Texas Tech University Health Sciences Center. El Paso, Texas Dec 13, 2017
4. Aligning evidence with preferences: Methodological Challenges and Opportunities Dartmouth-Hitchcock Medical Center, Dartmouth, New Hampshire, June 15, 2016
5. Aligning evidence with preferences: Methodological Challenges and Opportunities Department of Health Services and Research, Michael De-Bakey VA and Baylor University, Houston, Texas, May 16, 2016.
6. Aligning evidence with preferences: Methodological Challenges and Opportunities Meyers Primary Care Institute and Department of Family and Community Medicine, University of Massachusetts, Massachusetts, March 31 and June 9, 2016.
7. Aligning evidence with preferences: Methodological Challenges and Opportunities VA Center for Chronic Disease and Outcomes Research, Minnesota VA, March 2016.
8. Aligning evidence with preferences: Methodological Challenges and Opportunities Department of Medicine. University of Central Florida, Orlando, Florida, November 2015.
9. Aligning evidence with preferences: Methodological Challenges and Opportunities Center for Health Policy and Research Grand Rounds. UC Davis, Sacramento California, Oct 9, 2015.
10. Aligning evidence with preferences: Methodological Challenges and Opportunities Center for Evidence and Outcomes, Agency for Health Care Research and Quality. Gaithersville Maryland, August 31, 2015.
11. Risks of Spiriva Respimat outweigh its benefit: A Debate. Inhalation Asia, University of Hong Kong, Department of Pharmacology and Pharmacy, Hong Kong. 2013
12. GLP-1-based therapies and risk of pancreatitis. Center for Clinical Epidemiology and Biostatistics Seminar Series, University of Pennsylvania Philadelphia, Pennsylvania. 2013
13. Visiting Professor. Department of Medicine. University of Alabama. 2013
14. Value based health care: Can shared decision making methods get us there? Center for Value and Effectiveness, Medicine Institute, Cleveland Clinic, Noon Conference.2013
15. Role of Multi-criteria decision analysis in regulatory policy. Stanford Prevention Research Center, Stanford University, Palo Alto, Stanford, California. 2013
16. Role of Multi-criteria decision analysis in regulatory policy. South Carolina College of Pharmacy, Columbia, South Carolina.2013
17. Role of Multi-criteria decision analysis in regulatory policy. Department of Medicine. UC Davis, Sacramento, California.2013
18. Role of Multi-criteria decision analysis in regulatory policy. Department of Clinical Sciences, UT Southwestern, Dallas, Texas.2013
19. Role of Multi-criteria decision analysis in regulatory policy. Department of Medicine, Geisinger Medical Center, Danville, Pennsylvania. 2013

20. Weighing benefits and risks: Role of shared decision making in type 2 diabetes. CTSA Grand Rounds, Mayo Clinic, Rochester, Minnesota. 2013
21. Are long-acting muscarinic agents safe for patients with COPD: A Debate. Airway Vista, Asan Medical Center, Seoul, Korea
22. Academia and industry collaboration for cardiovascular risk mitigation. CBI and Applied Clinical Trials. 6th Annual Summit, Closing Address. Ritz Carlton, Arlington, Virginia.2012
23. Varenicline: Where are we today? Tobacco Disease Research Program, UCSF. San Francisco California. Varenicline debate.2012
24. The Maoist Insurgency in Nepal: Health Systems Challenges and Opportunities Conference on Health in Fragile States: Challenges for the Next Decade. United States Institute of Peace. Washington DC.2011
25. Standards of Care and the Role of Community Advocacy in Clinical Trials. Clinical Research in Developing Countries, Third Annual Marcus Evans Conference, Washington, DC.2008
26. Nepal-A Case study. Integrating public health methods into Conflict Analysis. Norman Patterson School of International Affairs, Carleton University, Ottawa, Canada.2007

Local/Regional Presentations

1. Development and Evaluation of the ALgorithm CErtainty Tool KIT (ACE-IT) to evaluate safety outcomes using electronic medical record and claims-based algorithm. Department of Family Medicine and Community Health 2023. Monthly Research Forum. January 20, 2023.
2. Oral direct acting antivirals and the incidence or recurrence of hepatocellular carcinoma. Research Seminar Series, Department of Family Medicine, and Community Health. University of Massachusetts Medical School. June 15. 2018
3. Safety of novel anticoagulants vs warfarin- a case study using complementary study designs. Quantitative Health Sciences, University of Massachusetts Medical School, February 28, 2017
4. GLP-1-based therapies and risk of pancreatic adverse events. University of Maryland, Division of Endocrinology, Metabolism and Nutrition, Grand Rounds, Baltimore, Maryland. 2013
5. Thiazolidinediones and Patient-Oriented Outcomes in Type 2 Diabetes, GIM Grand Rounds. Johns Hopkins University School of Medicine. 2012
6. Patient-Centered Benefit and Risk Assessment. Center for Health Services and Outcomes Research. Johns Hopkins University 2012
7. Varenicline and cardiovascular and neuropsychiatric adverse events: Do benefits outweigh risks? Welch Center Grand Rounds. Johns Hopkins University. 2011
8. The new wave, HIV, Human Rights and Men who have Sex with Men in Nepal. Johns Hopkins Bloomberg School of Public Health, 2011.
9. Network Meta-analysis and Serious Adverse Events. Network Meta-Analysis Methods Workshop. Johns Hopkins Bloomberg School of Public Health. 2010
10. Thiazolidinediones and Cardiovascular Outcomes in Type 2 Diabetes. Internal Medicine Grand Rounds. Wake Forest University School of Medicine, 2008
11. How Safe Are Our Drugs and How Do We Know? North Carolina ACP, Durham.2008
12. Clinical Pathologic Conference. Internal Medicine Grand Rounds. Wake Forest University School of Medicine, 2007

13. Globalization and Health Equity: An emerging Challenge for Academic Medicine. Internal Medicine Grand Rounds. Wake Forest University School of Medicine, 2007
14. Thiazolidinediones and Cardiovascular Disease: The Seduction of Common Sense. Epidemiology Seminar Series, Public Health Sciences. Wake Forest University 2007

National/International Workshops

1. ICPE International Meeting Copenhagen, Denmark, Copenhagen. Safety of antidiabetic medication oral presentation (Moderator). August 28, 2022
2. M Hernan, T Wilke, EJ Mills, S Singh Head-to-head comparisons of therapies using real world data: What is needed to emulate target trials. ICPE Virtual meeting 2020 (Panelist)
3. Ulka Campbell, Sengwi Kim, Sengwee Toh, Seamus Kent, Jeffrey Brown, Sonal Singh, Carla Rodriguez-Watson. What Do Real World Data Validation Best Practices Look Like? Operationalizing Guidance for Real World Studies intended for Decision-Making. 38th International Society of Pharmacoepidemiology, Annual Meeting, Copenhagen, Denmark. Aug 28, 2022. (Panelist)
4. ISPOR National Meeting. Head-to-Head Comparisons using Real World Data (RWD): Is the era of network of meta-analysis over. [Moderator and Chair] Virtual Meeting. May 18, 2020
5. ISPOR National Meeting, Next Generation Comparative Effectiveness Research- Are we getting organized to facilitate research for the individual patient? Washington, DC May 24, 2016 (workshop)
6. SGIM national meeting, developing high-quality search strategies for systematic reviews. 2010
7. SGIM national meeting, Systematic Review. 2009

Peer reviewed Original Research Publications

*Mentees **

*Lead methodologist ***

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| 1. Cocoros NM, Gurwitz JH, Cziraky MJ, Granger CB, Harkins T, Haynes K, Li X, Parlett L, Seeger JD, Singh S , McMahon-Walraven CN, Platt R. Pragmatic guidance for embedding pragmatic clinical trials in health plans: Large simple trials aren't so simple. Clin Trials. 2023 Jun 15;17407745231160459. doi: 10.1177/17407745231160459. Epub ahead of print. PMID: 37322894. |
| 2. Fisher KA, Nguyen N, Fouayzi H, Crawford S, Singh S , Dong M, Wittenberg R, Mazor KM. From COVID-19 Vaccine Hesitancy to Vaccine Acceptance: Results of a Longitudinal Survey. Public Health Rep. 2023 May 27;333549231176006. doi: 10.1177/00333549231176006. Epub ahead of print. PMID: 37243439. |
| 3. Reis G, Dos Santos Moreira Silva EA, Medeiros Silva DC, Thabane L, de Souza Campos VH, Ferreira TS, Quirino Dos Santos CV, Ribeiro Nogueira AM, Figueiredo Guimaraes Almeida AP, Cançado Monteiro Savassi L, de Figueiredo Neto AD, Bitarões C, Cruz Milagres A, Diniz Callegari E, Campos Simplicio MI, Barra Ribeiro L, Oliveira R, Harari O, Wilson LA, Forrest JI, Ruton H, Sprague S, McKay P, Guo CM, Guyatt GH, Rayner CR, Boulware DR, Ezer N, Lee TC, McDonald EG, Bafadhel M, Butler C, Rodrigues Silva J, Dybul M, Mills EJ; TOGETHER Investigators ; Oral Fluvoxamine With Inhaled Budesonide for Treatment of Early-Onset COVID-19 : A Randomized Platform Trial. <i>Ann Intern Med</i> 2023 May;176(5):667-675. PMID: 37068273; PMCID: PMC10111398. |
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Correspondence

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Major curricular offerings

2 credit Course in comparative effectiveness research for the Johns Hopkins ICTR 2015-2016

Biography

Sonal Singh MD, MPH, FACP received his MD from Patna Medical College India (1998) and completed his internal medicine residency training at Unity Health System, affiliate of Strong Memorial Hospital Rochester, NY. He is a Diplomate of the ABIM and a Fellow of the American College of Physicians. He obtained an MPH from Johns Hopkins Bloomberg School of Public Health (2008) and completed research training at the Johns Hopkins Hospital as a Junior Faculty Research Scholar supported by the NIH. He has taught and held faculty appointments at Wake Forest University School of Medicine and Johns Hopkins University School of Medicine and Public Health. He was the Associate Director for the Center for Drug Safety and Effectiveness and core faculty Evidence Based Practice Center and the Center for Public Health and Human Rights at Johns Hopkins University. He has received the Tinsley R Harrison Teaching Award for Education at Wake Forest University, Mid-Atlantic Society of General Internal Medicine Clinician Investigator of the Year Award, the Bruce P Squires Award for the best research paper of the year from the Canadian Medical Association Journal. His research has been published in leading medical journals such as the New England Journal of Medicine, Journal of the American Medical Association, British Medical Journal and The Lancet. These have been

featured in Nature Medicine, NYTIMES, CNN, Washington Post, and the WSJ. His work has been supported by the National Institute of Health, Food and Drug Administration, Agency for HealthCare Research and Quality, Patient Centered Outcomes Research Institute, the World Health Organization International Agency for Research on Cancer and the World Bank. He is a practicing general internist with a passion for managing patients with complex medical conditions.

Research and Clinical Interests

Dr. Singh is an internal medical specialist and epidemiologist specializing in assessing the safety of medications. He conducts clinical research with a focus on evidence synthesis, pharmacoepidemiology and shared decision making. He has led and participated in many impactful studies which have been incorporated into national and international guidelines on the treatment of chronic conditions. His research focusses on improving the safe use of medications for patients with chronic conditions. He has also led several efforts to improve the methodologic quality of studies that assess the safety and effectiveness of medications. He has also contributed to studies of developing new tools for measurement of human rights violations.

Personal Statement

I believe in making shared decisions about treatment after discussing patient's preferences and preferences. I believe that effective and safe treatments should improve quality of life and clinical outcomes along with any laboratory markers of disease. I try to understand patients' perspective on treatment. I deliver care in partnership with a highly collaborative and competent group of physicians, nurses, and staff at UMass Chan Medical School where we offer the best options for our patients.

EXHIBIT B

Trial Testimony

I have not provided trial testimony.

Depositions (last four years)

1. *Coates v. United States*, 3:18-cv-314 (W.D. Ky.): I have provided expert report and deposition on behalf of the plaintiff on July 16, 2020.
2. *In re: Tasigna (Nilotinib) Products Liability Litigation*, MDL No. 3006 (U.S. District Court for the Middle District of Florida): I have provided expert report and deposition on February 2, 2023 on behalf of the plaintiff.
3. *Van Foutch and Mary Foutch v. Jonathan Wilks MD and OU Medical Center*, Case No. CJ-20212934 (District Court of Oklahoma City): I have provided deposition on behalf of the defendants on the medicolegal standard of care for treatment of Rocky Mountain Spotted fever.
4. *Johnson & Johnson Talcum Powder Product Marketing, Sales Practices and Products Liability Litigation*, 3:16-md-2738-MAS-RL (U.S. District Court of New Jersey): I have provided an expert report and deposition on behalf of the plaintiff on April 4, 2024.